**Supporting Statement - Part A**
**External Quality Review (EQR) of Medicaid Managed Care, EQR Protocols, and Supporting Regulations in 42 CFR 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370**
**CMS-R-305, OMB 0938-0786**

This package is associated with a June 1, 2015 NPRM (CMS-2390-P; RIN 0938-AS25).

## Background

A proposed rule concerning external quality review (EQR) of Medicaid managed care organizations (MCOs) was published on December 1, 1999. (64 FR 67223) The EQR regulation implemented (1) section 1932(c)(2) of the Social Security Act (the Act), which was enacted in section 4705(a) of the Balanced Budget Act of 1997 (BBA), and (2) section 1903(a)(3)(C)(ii) of the Act, which was enacted in section 4705(b) of the BBA. Under section 1932(c)(2) each contract between a state Medicaid agency (state agency) and an MCO must provide for an annual EQR of the quality outcomes, the timeliness of, and access to, the services for which the MCO is responsible under the contract. Section 1903(a)(3)(C) provides enhanced matching for these activities. The final rule was published on January 24, 2003; it expanded the application of the EQR provisions to prepaid inpatient health plans (PIHPs) and to other risk comprehensive contracts states have with organizations exempt from 1903(m), such as certain health insuring organizations (HIOs).

As noted in the 2015 Unified Agenda, CMS has initiated a managed care Notice of Proposed Rule Making CMS-2390-P to modernize Medicaid managed care external quality review provisions and apply them to prepaid ambulatory health plans (PIHPs). This revised CMS-R-305 will align protocol activities to the supporting regulations in this NPRM.

*External Quality Review*
The annual EQR is to be conducted by an independent entity (external quality review organization, EQRO) that meets the qualifications set forth in these regulations. State agencies may use information about an MCO, PIHP, or PAHP, obtained through a Medicare or private accreditation review, in place of information generated through the EQR-related activities, if such activities would duplicate the activities under the Medicare or private accreditation review. Further, and consistent with BBA provisions, states may exempt certain MCOs from the annual EQR process.

The BBA provisions require that the results of the EQR (which are referred to as EQR technical reports) be made publicly available; CMS-2390-P would require states to post EQR technical reports on the state's website, in addition to providing the reports such parties as participating health care providers, enrollees and potential enrollees of the MCO upon request. The BBA also authorizes the payment of enhanced Federal financial participation at the 75 percent rate for expenditures on EQR (including the production of EQR results) and EQR-related activities performed on MCOs and conducted by EQROs..

*EQR Activities and Protocols*

States that contract with MCOs, PIHPs, and PAHPs to deliver Medicaid services would conduct an EQR of each plan each year. There are three mandatory EQR-related activities: validation of performance improvement projects; validation of performance measures; and a compliance review once every three years. CMS-2390-P would add a fourth mandatory activity, validation of network adequacy. There are five optional EQR-related activities, the data from which must be included in a state's EQR if the state elects to conduct the activity: validation of encounter data; administration or validation of consumer or provider surveys; calculation of additional performance measures; additional performance improvement projects; and focus studies. States, their contractors that are not MCOs, PIHPs, or PAHPs, or EQROs must conduct the EQR-related activities either using the EQR protocols or using methods consistent with these protocols.

Through a competitive procurement, we awarded a contract to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to develop the original protocols for external quality review activities. A Federal Register notice announcing their completion was published on November 23, 2001. The Federal Register notice served to comply with the Paperwork Reduction Act (PRA) and provided the public the opportunity to comment on the burden estimate or any other aspect of the protocols. The public comment period ended on January 22, 2002. The Office of Management and Budget required that the comments and responses on the protocols be included in the final EQR rule. We received comments from 13 organizations; these were reviewed and responses included in the preamble to the final rule.

The PRA approval of the protocols was renewed without change in 2006 and in 2009. At the time of the 2009 renewal, CMS was aware of the need to revise the protocols at a later time due to their use in the then newly-required Children's Health Insurance Program (CHIP) EQR reviews.

On July 1, 2010, CMS entered a contract with Provider Resources, Inc. (PRI) to revise the EQR Protocols for the first time since they were drafted in 2002. The revision was financed by CHIPRA funds and a principal reason for the revision was to add CHIP material to the protocols which had been designed for use in the Medicaid program. The revision also addressed numerous changes in law and quality practices beyond just the changes related to CHIPRA, including recommendations to voluntarily align with quality reporting opportunities under HITECH provisions of the American Recovery and Reinvestment Act of 2009, and the Affordable Care Act of 2010. The contract concluded at the end of 2010 and PRI delivered the revised protocols to CMS. The revised EQR Protocols received OMB approval in September 2012 for a three-year period, which expires September 30, 2015.

There are no proposed changes at this time to the EQR protocols. Following finalization of CMS-2390-P, we anticipate revising the EQR protocols to account for changes in regulation and quality review processes since 2012.

## A. Justification

1. Need and Legal Basis

Section 1932(c)(2)(A)(iii) requires that the Secretary have protocols developed to be used in EQRs.

Section 1932(c)(2)(A)(iv) requires that the results of EQR be made available to participating health care providers, enrollees and potential enrollees of the MCO.

2. Information Users

The law requires that the state agency provide to the EQRO information from the EQR-related activities, obtained through methods consistent with the Protocols specified by CMS (or with information from the Medicare or private accreditation review, in cases where the state uses the nonduplication provision). Information from EQR-related activities is generated by an EQRO, other state contractor that is not an MCO, PIHP, or PAHP, or the state, and is used by the EQRO to determine the quality of care furnished by an MCO.

The regulation extends the availability of the results of EQR to the public. In addition to responding to requests, states must post the EQR technical reports on their websites. This allows Medicaid enrollees and potential enrollees to make informed choices regarding the selection of their providers. It also allows advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to Medicaid beneficiaries enrolled in Medicaid MCOs, PIHPs, and PAHPs.

With respect to the nonduplication provision and the provision that allows for the exemption of EQR, these provisions do not relieve the state of its responsibility to ensure and monitor the access, timeliness, and quality of services are provided by the MCO, PIHP, or PAHP. Thus, information from the accreditation and Medicare review activities must be made available to the states agency in order for the state agency to use the information in its oversight of these organizations.

3. Use of Information Technology

The information is collected by the states. The decision as to whether or not collection methods can be improved with newer technology will be up to the states. Presently, states submit these reports to CMS by email. No signature, electronic or written, is required on the document.

4. Duplication of Efforts

These information collection requirements do not duplicate similar information collections. Rather, the intent is to provide states with an option to not have to duplicate Medicare or private accreditation review activities, thus enabling the state to minimize duplication of requirements placed on MCOs, PIHPs, and PAHPs with whom they contract.

5. Small Businesses

These information collection requirements do not affect small businesses.

6. Less Frequent Collection

As EQR by statute is an annual requirement, the information must be collected annually. If CMS were not to require states to collect this information annually, the states would be in violation of the law. Information from the state EQR technical reports is also used to inform the Annual Secretary's Report on Quality of Care for Children, required by CHIPRA Section 401(c)(B) (Annual State Reports Regarding State-Specific Quality of Care Measures Applied Under Medicaid or CHIP) and the Annual Secretary's Report on Quality of Care for Adults, required by Affordable Care Act Section 2701 (Adult Health Quality Measures).

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The NPRM is serving as the 60-day Federal Register notice which published on June 1, 2015 (80 FR 31098). The NPRM was placed on public inspection on May 26 whereby comments are due July 27.

The enactment of the Children's Health Insurance Reauthorization Act on February 6, 2009, has resulted in new EQR requirements for States. State Children's Health Insurance Programs that utilize managed care organizations or prepaid health insurance plans will now also be required to comply with the managed care requirements for external quality reporting. As statutorily mandated, CMS consulted with state Medicaid agencies as well as other stakeholders such as advocacy organizations and other experts in quality improvement regarding the development of the EQR protocols. This was done at the time of the original drafting of the Protocols in 2002 and was also part of the contract requirements with PRI as they drafted the revisions in 2010. Comments obtained from the March 13, 2009, Federal Register notice, were used by PRI in the revision process. We also solicited public comments on the revised protocols during the 60-day (February 17, 2012) and 30-day (May 31, 2012) comment periods prior to OMB approval of the revised Protocols in September 2012.

9. Payment/Gift to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected as a result of these laws will be provided directly to states and will be subject to state-like freedom of information requirements. However, as per Section 1932(c)(2)(A)(iv) of the Act, the results of EQR may not be made available in a manner that discloses the identity of any individual patient.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates

*Wage Estimates*

To develop burden estimates, we used data from the U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

| Occupation Title | Occupation Code | Mean Hourly Wage ($/hr) | Fringe Benefit (at 100%) ($/hr) | Adjusted Hourly Wage ($/hr) |
|---|---|---|---|---|
| Business Operations Specialist | 13-1000 | 29.66 | 29.66 | 53.32 |
| Computer Programmer | 15-1131 | 36.80 | 36.80 | 73.60 |
| General and Operations Mgr | 11-1021 | 63.86 | 63.86 | 127.72 |
| Office and Administrative Support Worker | 43-9000 | 14.96 | 14.96 | 29.92 |

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

*Burden Summary*

Overall, the annualized burden for the private sector for external quality review is **29,286 hr** and **$1,518,086.52** for the estimated 522 MCOs, PIHPs, and PAHPs.

The overall annualized burden for the public sector for external quality review is **227,683 hr** and **$17,012,168.52** for the estimated 40 states.

*Proposed Burden Estimates*

Section 438.350 External quality review

There is no burden associated with this section, which describes the annual external quality review which must be conducted for each contracted MCO, PIHP, and PAHP.

Section 438.350 would add PAHPs to the list of affected entities in §438.350(a)(1) and (2). The addition of PAHPs to the EQR process would require the nine states with PAHPs and existing EQRO contracts to modify their existing EQRO contracts. The estimated 3 states with PAHPs that do not currently have an EQRO contract would need to enter into a contract with an EQRO.

Section 438.352 External quality review protocols

There is no burden associated with this section, which describes the components of the EQR protocols, which are the instructions for the EQR-related activities described in §438.358. States, their contractors that are not MCOs, PIHPs, or PAHPs, or EQROs must conduct the EQR-related activities either using the EQR protocols or using methods consistent with these protocols. The burden associated with reading and following the EQR protocols to conduct the EQR-related activities is captured in the burden for §438.358.

Section 438.358 Activities related to external quality review

This section describes the mandatory and optional EQR-related activities, which may be performed by the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO. It also describes when EQROs may, at state's discretion, provide technical assistance to MCOs, PIHPs, and PAHPs to assist in the performance of mandatory and optional EQR-related activities.

Section 438.358(b) describes the mandatory EQR-related activities. These activities may be conducted by the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO; we will describe the burden assuming that the state conducts these activities. The burden associated with these activities would be the time and effort for a state to conduct and document the findings of the four mandatory activities: (1) the annual validation of PIPs conducted by the MCO, PIHP, or PAHP, (2) the annual validation of performance measures calculated by the MCO, PIHP, or PAHP, (3) a review of MCO, PIHP, or PAHP compliance with structural and operational standards, performed once every three years, and (4) validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months. Each of the activities would be conducted on the 552 MCOs, PIHPs, and PAHPs that we estimate are currently providing Medicaid services.

The types of services provided by MCOs, PIHPs, and PAHPs and the number of PIPs conducted and performance measures calculated will vary. The currently approved burden under control number 0938-0786 (CMS-R-305) for these three activities assumes

that each of the then-estimated 458 MCOs and PIHPs validate one PIP by a professional at $63/hr for 65 hr, validate one performance measure by a professional at $63/hr for 53 hr, and complete an annual a compliance review by a professional at $63/hr for 361 hr. The currently approved annual burden is 219,382 hr (479 hr x 458 MCOs and PIHPs) and $13,821,066 (219,382 hr x $63/hr). However, based on recent experience, we estimate that each MCO or PIHP will conduct 3 PIPs, each PAHP will conduct 1 PIP, and that each MCO, PIHP, or PAHP will calculate 3 performance measures. Furthermore, using the time estimates developed for MCOs and PIHPs for the currently approved burden estimates under control number 0938-0786 (CMS-R-305) (and assuming that the same time estimates will also apply to PAHPs), we estimate it would take an average of 65 hr/PIP validation, 53 hr/performance measure validation, and 361 hr/compliance review (occurs once every three years) for a business operations specialist, at $53.32/hr, to conduct the mandatory EQR activities. For MCOs and PIHPS, we estimate an annual state burden of **242,367.3 hr** (511 MCOs and PIHPs x [(65 hr x 3 PIPs) + (53 hr x 3 performance measures) + (361 hr / 3 year)]) and **$12,923,024.44** (242,367.3 hr x $53.32/hr) for the first three mandatory EQR-related activities.

For PAHPs, we estimate an annual state burden of **14,116.3 hr** (41 PAHPs x 344.3 hr [(65 hr x 1 PIPs) + (53 hr x 3 performance measures) + (361 hr / 3 years)]) and **$752,681.12** (14,116.3 hr x $53.32/hr) for the first three mandatory EQR-related activities.

Section 438.358(b)(4) would establish a new mandatory activity (the fourth) to validate MCO, PIHP, and PAHP network adequacy during the preceding 12 months. States would conduct this activity for each MCO, PIHP, and PAHP. Given that this is a new activity, we do not have historic data on which to base an hourly burden estimate for the network validation process. We estimate that it will take less time than the validation of a PIP but more time than the validation of a performance measure. Therefore, we estimate an annual state burden of 60 hr at $53.32/hr for a business operations specialist to support the validation of network adequacy activity. In aggregate, we estimate **33,120 hr** (552 MCOs, PIHPs, and PAHPs x 60 hr) and **$1,765,958.40** (33,120 hr x $53.32/hr) for the validation of network adequacy activity.

To summarize, for the proposed four mandatory EQR-related activities, we estimate an annual aggregated state burden of **70,221.6 hr** [(22,985.3 hr + 14,116.3 hr + 33,120 hr) - 219,382 hr] and **$1,620,597.96** [(-$898,041.56 + $752,681.12 + $1,765,958.40) - $13,821,066].

The burden associated with § 438.358(b)(1) through (4) would also include the time for an MCO, PIHP, or PAHP to prepare the information necessary for the state to conduct the mandatory EQR-related activities. We estimate that it would take each MCO, PIHP, or PAHP 200 hr to prepare the documentation for these four activities, half (100 hr) at $53.32/hr by a business operations specialist and half (100 hr) at $29.92/hr by an office and administrative support worker. In aggregate, we estimate an annual private sector burden of **110,400 hr** (552 MCOs, PIHPs, and PAHPs x 200 hr) and **$4,594,848** [(55,200 hr x $53.32/hr) + (55,200 hr x $29.92/hr)]. However, the currently approved burden

under control number 0938-0786 (CMS-R-305) estimates 160 hr per MCO or PIHP to prepare the information for the three existing mandatory EQR-related activities (§438.358(b)(1) through (3)), half by a professional at $63/hr and half by clerical staff at $12/hr, The currently approved burden for information preparation is 73,280 hr (438 MCOs and PIHPs x 160 hr) and $2,748,000 [(36,640 hr x $63/hr) + (36,640 hr x $12/hr)]. When comparing the currently approve burden against this rule's proposed burden, we estimate a net burden of **37,120 hr** (110,400 hr - 73,280 hr) and **$1,846,848** ($4,594,848 - $2,748,000) for the preparation of information for the mandatory EQR-related activities described in §438.358(b)(1) through (4).

Section 438.358(c) describes the five optional EQR-related activities: (1) validation of client level data (such as claims and encounters), (2) administration or validation of consumer or provider surveys, (3) calculation of performance measures, (4) conduct of PIPs, and (5) conduct of focused studies. As with the mandatory activities described in § 438.358(b), these activities may be conducted by the state, its agent that is not an MCO, PIHP, or PAHP, or an EQRO, but for the purposes of this burden estimate we assume that the state conducts the activities.

We have no data to estimate the hours associated with how long it will take to conduct the optional EQR activities. Without that information, we estimate is that it would take 350 hr to validate client level data and 50 hr to validate consumer or provider surveys. We estimate it would take three times as long to calculate performance measures as it takes on average to validate (159 hr) and three times as long to conduct PIPs and focused studies as it takes on average to validate PIPs (195 hr). We also estimate that it would take three times as long to administer a consumer or provider survey than it takes to validate a survey (150 hr).

The currently approved burden under control number 0938-0786 (CMS-R-305) uses state-reported data from 2001 to estimate that states will: (1) validate the encounter data of 69 percent (316) of MCOs and PIHPs, (2) administer or validate consumer or provider surveys of 43 percent (197) of MCOs and PIHPs, (3) calculate performance measures of 29 percent (133) of MCOs and PIHPs, (4) conduct PIPs of 38 percent (174) of MCOs and PIHPs, and (5) conduct focused studies of 76 percent (348) of MCOs and PIHPs. Using the hourly estimates (above) for each task and assuming the work is completed by a professional at $63/hr, CMS-R-305 estimates a total burden of 240,759 hr and $15,167,817. However, based on our review of EQR technical report submissions since the original promulgation of these regulations, we have observed that many states do not conduct the optional EQR-related activities as frequently as assumed in our original estimates. While the exact states and number vary from year to year, we have not observed participation at the level observed in 2001 state-reported data. Therefore, we revise our estimate and assume that 10 percent (51) of MCOs and PIHPs will be subject to each of the optional EQR-related activities. Regarding the administration or validation of consumer or provider surveys, we assume that half of the MCOs and PIHPs (25) will administer surveys while half (26) will validate surveys. We also estimate that a mix of professionals will work on each optional EQR-related activity: 20 percent by a general and operations manager ($127.72/hr), 25 percent by a computer programs ($73.60/hr),

and 55 percent by a business operations specialist ($53.32/hr).

To validate client level data, we estimate **17,850 hr** (51 MCOs and PIHPs x 350 hr) and **$1,307,869.50** [(17,850 hr x 20 percent x $127.72/hr) + (17,850 hr x 25 percent x $73.60/hr) + (17,850 hr x 55 percent x $53.32/hr)]. To administer consumer or provider surveys, we estimate **3,750 hr** (25 MCOs and PIHPs x 150 hr) and **$274,762.50** [(3,750 hr x 20 percent x $127.72/hr) + (3,750 hr x 25 percent x $73.60/hr) + (3,750 hr x 55 percent x $53.32/hr)]. To validate consumer or provider surveys, we estimate **1,300 hr** (26 MCOs and PIHPs x 50 hr) and **$95,251** [(1,300 hr x 20 percent x $127.72/hr) + (1,300 hr x 25 percent x $73.60/hr) + (1,300 hr x 55 percent x $53.32/hr)]. To calculate performance measures, we estimate **8,109 hr** (51 MCOs and PIHPs x 159 hr) and **$594,146.43** [(8,109 hr x 20 percent x $127.72/hr) + (8,109 hr x 25 percent x $73.60/hr) + (8,109 hr x 55 percent x $53.32/hr)]. To conduct PIPs, we estimate **9,945 hr** (51 MCOs and PIHPs x 195 hr) and **$728,670.15** [(9,945 hr x 20 percent x $127.72/hr) + (9,945 hr x 25 percent x $73.60/hr) + (9,945 hr x 55 percent x $53.32/hr)]. To conduct focused studies, we estimate **9,945 hr** (51 MCOs and PIHPs x 195 hr) and **$728,670.15** [(9,945 hr x 20 percent x $127.72/hr) + (9,945 hr x 25 percent x $73.60/hr) + (9,945 hr x 55 percent x $53.32/hr)]. In aggregate, the annual burden for optional EQR-related activities for MCOs and PIHPs is **50,899 hr** (17,850 hr + 3,750 hr + 1,300 hr + 8,109 hr + 9,945 hr + 9,945 hr) and **$3,729,369.73** [(50,899 hr x 20 percent x $127.72/hr) + (50,899 hr x 25 percent x $73.60/hr) + (50,899 hr x 55 percent x $53.32/hr)].

Section 438.358(c) would also be revised to include PAHPs. Since PAHPs are not currently subject to EQR, we do not have any data on which to base an estimate regarding how states would apply the optional EQR-related activities. Therefore, we will apply the time, wage, and participation estimates developed for MCOs and PIHPs to PAHPs. To validate client level data, we estimate **1,400 hr** (4 PAHPs x 350 hr) and **$102,578** [(1,400 hr x 20 percent x $127.72/hr) + (1,400 hr x 25 percent x $73.60/hr) + (1,400 hr x 55 percent x $53.32/hr)]. To administer consumer or provider surveys, we estimate **300 hr** (2 PAHPs x 150 hr) and **$21,981** [(300 hr x 20 percent x $127.72/hr) + (300 hr x 25 percent x $73.60/hr) + (300 hr x 55 percent x $53.32/hr)]. To validate consumer or provider surveys, we estimate **100 hr** (2 PAHPs x 50 hr) and **$7,327** [(100 hr x 20 percent x $127.72/hr) + (100 hr x 25 percent x $73.60/hr) + (100 hr x 55 percent x $53.32/hr)]. To calculate performance measures, we estimate **636 hr** (4 PAHPs x 159 hr) and **$46,599.72** [(636 hr x 20 percent x $127.72/hr) + (636 hr x 25 percent x $73.60/hr) + (636 hr x 55 percent x $53.32/hr)]. To conduct PIPs, we estimate **780 hr** (4 PAHPs x 195 hr) and **$57,150.60** [(780 hr x 20 percent x $127.72/hr) + (780 hr x 25 percent x $73.60/hr) + (780 hr x 55 percent x $53.32/hr)]. To conduct focused studies, we estimate **780 hr** (4 PAHPs x 195 hr) and **$57,150.60** [(780 hr x 20 percent x $127.72/hr) + (780 hr x 25 percent x $73.60/hr) + (780 hr x 55 percent x $53.32/hr)]. In aggregate, the total annual burden for optional EQR-related activities for PAHPs is **3,996 hr** (1,400 hr + 300 hr + 100 hr + 636 hr + 780 hr + 780 hr) and **$292,786.92** [(3,996 hr x 20 percent x $127.72/hr) + (3,996 hr x 25 percent x $73.60/hr) + (3,996 hr x 55 percent x $53.32/hr)].

<u>Section 438.360 Nonduplication of mandatory activities</u>

This section describes the circumstances under which the state may use information about an MCO, PIHP, or PAHP obtained from a Medicare or private accreditation review in place of information otherwise generated about the plan through the EQR-related activities described in § 438.358.

Section 438.360(a) would grant states the option to use the information obtained from a Medicare or private accreditation review of an MCO, PIHP, or PAHP in place of information otherwise generated from the three mandatory activities specified in § 438.358(b)(1) through (3). The proposed revisions would: (1) allow states to apply the non-duplication option to PAHPs, in addition to MCOs and PIHPs; (2) allow states to apply the non-duplication option to the validation of performance measures and PIPs, in addition to the compliance review, for all MCOs, PIHPs, and PAHPs; (3) remove current § 438.360(c), as there would no longer be a difference in the application of non-duplication to plans serving only dual eligibles; and (4) combine current § 438.360(b)(4) and (c)(4) into proposed § 438.360(c), to maintain a discussion of non-duplication as an element of the comprehensive quality strategy.

Section 438.360(b) would describe when a state could elect to use information from a Medicaid or private accreditation review in place of information that would otherwise be generated by the mandatory EQR-related activities in § 438.358(b)(1) through (3). The burden associated with non-duplication is the time and effort for an MCO, PIHP, or PAHP to disclose the reports, findings, and other results of the Medicare or private accreditation review to the state agency.

While states could elect to allow all 552 MCOs, PIHPs, and PAHPs to substitute information from a Medicare or private accreditation review for the three mandatory EQR-related activities specified at § 438.358(b)(1) through (3), in practice we find that states utilize this option infrequently. Therefore, we estimate that states would apply the non-duplication option to 10 percent (55) of MCOs (33), PIHPs (18), and PAHPs (4). The currently approved burden under control number 0938-0786 (CMS-R-305)) estimates that 336 MCOs and/or PIHPs take advantage of the nonduplication provision, requiring 8 hr at $37.50/hr per MCO or PIHP to disclose the necessary information to the state, for a total currently approved burden of 2,688 hr (336 MCOs and PIHPs x 8 hr) and $100,800 (2,688 hr x $37.50/hr). Since this appears to be an overestimate of the burden for MCOs and PIHPs, we estimate a revised annual private sector burden of 2 hr at $53.32/hr for a business operations specialist and 6 hr at $29.92/hr for an office and administrative support worker to disclose the necessary documentation to the state each year for a single MCO or PIHP. In aggregate, we estimate **408 hr** (51 MCOs and PIHPs x 8 hr) and **$14,594.16** [(51 MCOs and PIHPs x (2 hr x $53.32/hr) + (6 hr x $29.92/hr)]. Under this proposal, states could apply the nonduplication provisions to PAHPs. In aggregate, we estimate **32 hr** (4 PAHPs x 8 hr) and **$1,144.64** [4 PAHPs x (2 hr x $53.32/hr) + (6 hr x $29.92/hr)].

The process in section 438.360(b) would include having a state agency provide all of the reports, findings, and other results of the Medicare or private accreditation review to the appropriate EQRO. The currently approved burden under control number 0938-0786

(CMS-R-305) estimates that sharing the reports, findings, and results with EQROs for 336 MCOs and PIHPs would take states 8 hr at $37.50/hr per plan, for a total burden of 2,688 hr (336 MCOs x 8 hr) and $100,800 (2,688 hr x $37.50/hr). However, we estimate it would take, on average, 2 hr at $29.92/hr for an office and administrative support worker to disclose the necessary documentation to the appropriate EQRO. This represents a decrease in the estimated hourly burden for this task, as we believe that the use of electronic tracking and transmission tools has significantly decreased the hourly burden associated with state staff forwarding the documentation to the EQRO. In aggregate, we estimate an annual state burden of **110 hr** (55 MCOs, PIHPs, and PAHPs x 2 hr) and **$3,291.20** (110 hr x $29.92/hr) to forward non-duplication-related documentation to the EQROs.

Assuming that states would apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we estimate that this provision would offset the burden associated with § 438.358(b)(1) through (3) for 51 MCOs and PIHPs, and 4 PAHPs (since these activities would no longer be necessary for these 55 plans). Consistent with the estimates used in §438.358(b)(1) through (3), we estimate an aggregated offset of **–25,566.50 hr** [(-51 MCOs and PIHPs x 474.3 hr) + (-4 PAHPs x 344.3 hr)] and **-$1,363,205.78** (-25,566.50 hr x $53.32).

Additionally, the MCOs, PIHPs, and PAHPs subject to non-duplication would not have to prepare the documentation necessary for the three mandatory EQR-related activities. Based on the assumption in § 438.358(b) that an MCO, PIHP, or PAHP would need 200 hr to prepare the documentation for the four mandatory activities, we estimate that it would take 150 hr to prepare the documentation for the three activities subject to non-duplication, half (100 hr) at $53.32/hr by a business operations specialist and half (100 hr) at $29.92/hr by an office and administrative support worker. In aggregate, we estimate a decrease in annual private sector burden of **-8,250 hr** (-55 MCOs, PIHPs, and PAHPs x 150 hr) and **-$343,365** [(-4,125 hr x $53.32/hr) + (-4,125 x $29.92)].

Section 438.360(c) would require states to document, in the comprehensive quality strategy required at §431.502, which mandatory EQR-related activities it will apply the non-duplication provisions to, and why it believes these activities would be duplicative. Given that this is already standard practice for the 37 states that currently contract with MCOs and/or PIHPs, only the 3 states that contract only with PAHPs would have to revise their policies and procedures to include this in their comprehensive quality strategy. This section would also require states to document, in the comprehensive quality strategy required at §431.502, which mandatory EQR-related activities it will apply the non-duplication provisions to, and why it believes these activities would be duplicative. Given that this is already standard practice for the 37 states that currently contract with MCOs and/or PIHPs, only the three states that contract only with PAHPs would have to revise their policies and procedures to include this in their comprehensive quality strategy.

Section 438.362 Exemption from external quality review

This section describes the circumstances under which a state may exempt an MCO from

EQR.

Section 438.362 would be modified to reflect that PIHPs cannot be exempted from EQR, as they do not qualify as a MA Organization under part C of Title XVII of the Act or under section 1876, and they do not qualify as an MCO under section 1903(m). This would lead to a decrease in our estimate of the number of plans that might be exempt from the EQR process.

Under section 438.362, exempted MCOs would have to provide (annually) to the state agency the most recent Medicare review findings reported to the MCO by CMS or its agent. Of the approximately 335 MCOs, we estimate that approximately half (168) might provide Medicare services in addition to Medicaid services. Of these 168 MCOs that might potentially provide Medicare services in addition to Medicaid services, we further estimate that state agencies would allow approximately 10 percent (17) of the MCOs to be exempt from the EQR process.

We estimate an annual private sector burden of 8 hr (2 hr at $53.32/hr for a business operations specialist and 6 hr at $29.92/hr for an office and administrative support worker) for an MCO to prepare and submit the necessary documentation to the state agency. In aggregate, we estimate **136 hr** (17 MCOs x 8 hr) and **$4,864.72** (17 MCOs x [(2 hr x $53.32/hr) + (6 hr x $29.92/hr)]).

The currently approved burden under control number 0938-0786 (CMS-R-305) estimates that states would allow 10 percent (20) of the 202 MCOs (which might provide Medicare services in addition to Medicaid services) to be exempt from the EQR process, and that it would take each MCO approximately 8 hr at $37.50/hr to prepare the necessary materials for a total burden of **160 hr** (20 MCOs x 8 hr) and **$6,000** (160 hr x $37.50/hr).

Therefore, we estimate a net burden of **-24 hr** (136 hr – 160 hr) and **-$1,135.28** ($4,864.72 - $6,000).

Section 438.364 External quality review results

This section describes the minimum information that must be included in a state's annual EQR technical report which summarizes findings on access and quality of care. It also describes how the state must make this information available to the public, which includes a requirement that this action may not disclose the identity of any patient.

Section 438.364(a) would describe the information that would be included in the annual detailed technical report that is the product of the EQR. Section 438.364(a)(1)(iii) would specify that the EQR technical report include baseline and outcomes data regarding PIPs and performance measures. Many states already provide much of this information in their final EQR technical report. The burden of compiling this data for MCOs, PIHPs, and PAHPs is captured in § 438.358. Under section 438.364(a)(3), EQR technical reports would include recommendations on how the state can use the goals and objectives of its comprehensive quality strategy to support improvement in the quality, timeliness, and access to care for beneficiaries. We believe that states would amend their EQRO

contracts to address the changes to § 438.364(a). We estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to amend the EQRO contract. In aggregate, we estimate **20 hr** (40 states x 0.5 hr) and **$1,066.40** (20 hr x $53.32/hr).

Section 438.364(b)(1) would clarify that the EQRO would produce and submit to the state an annual EQR technical report, and that states may not substantively revise the report without evidence of error or omission, or permission from CMS. This is consistent with existing policy and should not pose a burden on the states or the private sector. The proposed April 30 deadline for the finalization and submission of EQR technical reports is consistent with existing sub-regulatory guidance.

While we do not anticipate that these changes would pose a significant burden on states or the private sector, we estimate that this provision may necessitate a change in a state's EQRO contract for approximately 10 states. In this regard, we estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to modify the EQRO contract. In aggregate, we estimate **5 hr** (10 states x 0.5 hr) and **$266.60** (5 hr x $53.32/hr).

Under section 438.364(b)(2), each state agency would provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. States would also make the most recent EQR technical report publicly available on the state's website, the burden for which is included in §438.10.

We believe that by making these reports available online, states would be able to significantly decrease the burden associated with responding to requests from the public for this information, as it will already be easily accessible. The burden associated with section is the time and effort for a state agency to furnish copies of a given technical report to interested parties. The currently approved burden under control number 0938-0786 (CMS-R-305) estimates a burden of 91,600 hr and $1,099,200. This assumed 329 MCOs and 129 PIHPs (for a total of 458), 25 requests per MCO or PIHP, and 8 hr to respond to each request by staff at $12/hr. In light of recent technological changes described above, we estimate an annual state burden of 5 min (on average) at $29.92/hr for an office and administrative support worker to disclose the reports (per request), and that a state would receive 5 requests per MCO, PIHP, or PAHP per year. In aggregate, we estimate **230 hr** [(552 MCOs, PIHPs, and PAHPs x 5 requests x 5 min) / 60 min] and **$6,881.60** (230 hr x $29.92/hr). Overall, we estimate a net burden of **-91,370 hr** (230 hr - 91,600 hr) and **-$1,092,318.40** ($6,881.60 - $1,099,200).

<u>Section 438.370 Federal financial participation (FFP)</u>
This section describes the availability of FFP for EQR and EQR-related activities.

Section 438.370(c) would have states submit their EQRO contracts to CMS for review and approval prior to claiming FFP at the 75 percent rate. Since most states already consult with CMS regarding EQRO contracts, we estimate only 12 states will need to

amend their policies and procedures to comply with this process. We estimate a one-time state burden of 0.5 hr at $53.32/hr for a business operations specialist to amend their state's policies and procedures. In aggregate, we estimate **6 hr** (12 states x 0.5 hr) and **$319.92** (6 hr x $53.32/hr).

The 12 states which do not currently work with CMS on their EQRO contracts would need to submit the EQRO contracts to CMS for review and approval if they plan to claim the enhanced 75 percent federal match. We estimate 0.25 hr at $29.92/hr for an office and administrative support worker to submit the EQRO contract to CMS. In aggregate, we estimate **3 hr** (12 states x 0.25 hr) and **$89.76** (3 hr x $29.92/hr).

13. Capital Costs

There are no capital or maintenance costs.

14. Cost to Federal Government

This collection involves both private sector (MCOs, PIHPs, and PAHPs) and public sector (state government).

Total annualized private sector costs are $1,518,086.52. Consistent with the assumptions used for the private sector match rate in the NPRM (CMS-2390-P), we assume that the private sector will pass long costs to states through their capitation rates and estimate a weighted Federal match rate of 58.44 percent (weighted for enrollment). Therefore, the Federal share for annualized private sector costs is $887,169.76.

There are two Federal match rates for EQR: 75 percent for EQR and EQR-related activities conducted by EQROs on MCOs, and 50 percent for EQR and EQR-related activities conducted on PIHPs and PAHPS by any entity, or on MCOs by non-EQROs.

Of the total annualized public sector costs ($17,012,168.52), we estimate that $12,032,463.28 will be eligible for the 75 percent Federal match rate and $4,979,706.24 will be eligible for the 50 percent Federal match rate. Therefore, the Federal share for annualized public sector costs is $11,514,199.83.

Total annualized Federal share (private and public sector) is $12,401,369.59.

15. Program or Burden Changes

There are no changes to the EQR protocols. Adjustments have been made to CMS-R-305 to account for: (1) changes to the regulations per CMS-2390-P (see detailed description in Section 12), (2) mathematical errors and estimate revisions in regards to the number of respondents, the type of respondents, annual responses, and annual hour burden, and (3) updated BLS job titles and wages.

We have removed the CHIP EQR burden from CMS-R-305 as under CMS-2390-P we propose the creation of a PRA package (CMS-10554, OMB 0938-New) which contains all of the CHIP managed care burden, including EQR.

The chart below summarizes, at the section level, the annualized changes to hour and cost burdens for CMS-R-305 as compared to the most recent available supporting statement estimates.

| CFR Section | Hours | | | Costs | | | Reason for Change |
|---|---|---|---|---|---|---|---|
| | Previous | Revised | Difference | Previous | Revised | Difference | |
| **438.350 EQR** | --- | --- | N/A | --- | --- | N/A | N/A |
| **438.352 EQR Protocols** | 451,288 | 0 | (451,288) | $40,850,590 | $0 | ($40,850,590) | • Estimate change: burden is more accurately captured under 438.358.<br>• PRA change: removal of CHIP EQR burden from this package and into CMS-10554 (OMB 0938-New). |
| **438.354 EQRO Qualifications** | --- | --- | N/A | --- | --- | N/A | N/A |
| **438.356 State EQR Contract Options** | --- | --- | N/A | --- | --- | N/A | N/A |
| **438.358 EQR-related activities** | 0 | 381,619 | 381,619 | 0 | $21,310,688.60 | $21,310,688.60 | • Regulatory change: addition of mandatory EQR-related activity, expansion of EQR to PAHPs.<br>• Estimate change: movement of burden from 438.352 to 438.358, number of entities. |
| **438.360 EQR Nonduplication** | 5,376 | (33,267) | (27,891) | $201,600 | ($1,687,540.78) | ($1,485,940.87) | • Regulatory change (expansion of EQR to PAHPs).<br>• Estimate change: developed estimate to offset EQR-related activity costs that would otherwise occur without nonduplication. |

| CFR Section | Hours | | | Costs | | | Reason for Change |
|---|---|---|---|---|---|---|---|
| | Previous | Revised | Difference | Previous | Revised | Difference | |
| **438.362 EQR Exemption** | 160 | 136 | (24) | $6,000 | $4,864.72 | ($1,135.28) | • Regulatory change: expansion of EQR to PAHPs. |
| **438.364 EQR Results** | 91,600 | 255 | (91,362) | $1,099,200 | $8,214.60 | ($1,091,874.07) | • Regulatory change: expansion of EQR to PAHPs, posting of EQR technical reports on states' websites.<br>• Estimate change: time required to respond to requests for EQR technical reports. |
| **438.370 FFP** | 0 | 3 | 3 hr | 0 | $136.56 | $136.56 | • Regulatory change: requiring submission of EQRO contracts to CMS for review in order to claim 75 percent match rate. |

16. Publication and Tabulation Dates

The EQR must, at a minimum, result in a detailed technical report that summarizes the findings on access and quality of care. This must include:

1) A description of the manner in which the data from the EQR-related activities were aggregated and analyzed, and the conclusions drawn by the EQRO regarding the quality, timeliness, and access to care provided by the MCO, PIHP, and PAHP;

2) Details for each EQR-related activity, including the objectives, technical methods of data collection and analysis, description of the data obtained (including performance measurement data for the validation of performance measures and performance improvement projects), and conclusions drawn from the data;

3) An assessment of the strength and weaknesses of each MCO, PIHP, and PAHP with respect to timeliness, access, and quality of the health care services furnished to Medicaid beneficiaries;

4) Recommendations for improving the quality of the services furnished by each MCO, PIHP, and PAHP, including how the state can target goals and objectives

in its comprehensive quality strategy (required under part 431, subpart I) to support improvement in the quality, timeliness, and access to services;

5) Comparative information about all MCOs, PIHPs, and PAHPs; and

6) An assessment of the degree to which each plan followed up on prior year's recommendations.

The annual EQR technical report will be submitted by the contracting EQRO to the state, which will then submit it to CMS, post it on the state's website, and provide this information upon request.

CMS will use the state-provided EQR technical reports in the development of the Annual Secretary's Report on Quality of Care for Children and the Annual Secretary's Report on Quality of Care for Adults.

CMS intends to maintain a list of hyperlinks on Medicaid.gov to states' websites where EQR technical reports are posted in order to improve public transparency.

17. Expiration Date

These information collection requirements do not lend themselves to an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.